UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,125	10/04/2004	Shalaby W. Shalaby	SHA-38-PCT-US	6610

29698 7590 05/10/2010

LEIGH P. GREGORY
PO BOX 168
CLEMSON, SC 29633-0168

EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,125	SHALABY, SHALABY W.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-8,12,and 17-18* is/are pending in the application.

4a) Of the above claim(s) *6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,8,12,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 2/1/2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1 and 12 under 35 U.S.C. 103(a) as being unpatentable over EP 0952171 (EP '171) in view of '893 in further view of '747 (US 5149747) is maintained.

Applicant argues that EP '171 is directed to liquid copolymers. One of ordinary skill in the art would recognize that liquid polymers could not be used as necessarily solid coatings for endovascular stents.

Applicant's arguments have been fully considered but are not found persuasive.

The Examiner maintains that the liquid compositions of EP '171 can be used as coatings for endovascular stents. US 20030083740 (cited in the previous office action) teaches room temperature liquids can be used as endovascular stents:

> "A 50 ml round bottom flask with a Teflon coated magnetic stirrer is flame dried under repeated cycles of vacuum and dry nitrogen. Two (2) g trimethylol propane, 11.68 g D,L-lactide, and 0.20 mg stannous octoate are charged to the flask. The flask is then heated to 165o C for 16 hours and then cooled. The liquid product is dissolved in 30 ml toluene and precipitated in large excess cold hexane. The precipitated polymer, which is a liquid at room temperature, is isolated and can be used in coating stents." (¶ 89).

As the art recognizes that liquids can be used in coating stents, the Examiner maintains that the liquid polymers of EP '171 can be used in coating stents.

The rejection of claims 1, 8 and 12 under 35 U.S.C. 103(a) as being unpatentable over EP 0952171 (EP '171) in view of US 5149747 ('747) in further view of US 5681846 ('846) is maintained for the reasons of record.

Applicant argues that EP '171 is directed to liquid copolymers. One of ordinary skill in the art would recognize that liquid polymers could not be used as necessarily solid coatings for endovascular stents. Applicant further argues that the use of maleic anhydride in the present invention leads to inserting a succinic acid residue into the polymer chain through a free radical reaction entailing the creation of a new C-C bond and not a C-O bond as is the case in '747.

The Examiner maintains that the liquid compositions of EP '171 can be used as coatings for endovascular stents. US 20030083740 (cited in the previous office action) teaches room temperature liquids can be used as endovascular stents:

> "A 50 ml round bottom flask with a Teflon coated magnetic stirrer is flame dried under repeated cycles of vacuum and dry nitrogen. Two (2) g trimethylol propane, 11.68 g D,L-lactide, and 0.20 mg stannous octoate are charged to the flask. The flask is then heated to 165o C for 16 hours and then cooled. The liquid product is dissolved in 30 ml toluene and precipitated in large excess cold hexane. The precipitated polymer, which is a liquid at room temperature, is isolated and can be used in coating stents." (¶ 89).

As the art recognizes that liquids can be used in coating stents, the Examiner maintains that the liquid polymers of EP '171 can be used in coating stents.

Regarding the introduction of a new C-C bond, it is noted that the features upon which applicant relies (i.e., that the use of maleic anhydride in the present invention leads to inserting a succinic acid residue into the polymer chain through a free radical reaction entailing the creation of a new C-C bond and not a C-O bond) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). EP '171 discloses hydrogel polyester copolymers and their utility in providing a protective barrier to prevent post-surgical adhesion, treatment of defects in conduits such as blood vessels, and controlled release of a biologically active agent for modulating cellular events such as wound healing and tissue regeneration (see abstract; ¶ 22-34). Triblock copolymers comprising a central polyoxyethylene segment and a terminal polyester segment formed from glyclide, lactide, and epsilon-caprolactone (cyclic monomers) are disclosed (see ¶ 53-57). Di-lactide/glycolide is exemplified (see Example I). The end groups can optionally be carboxylated by an acylation with an appropriate agent, such as succinic anhydride (see ¶ 54). EP '171 fails to disclose introduction of at least one carboxyl side group by free-

radically achieved maleation. '747 discloses that succinic anhydride, glutaric anhydride, and maleic anhydride are excellent acylating reagents for the preparation of esterified graft copolymers (see col 4, lines 51-54). It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to introduce the carboxyl side group by free-radically achieved maleation (i.e. reaction with maleic anhydride). EP '171 contemplates acylation of the terminal di-lactide/glycolide with an appropriate agent, and succinic anhydride (disclosed by EP '171), glutaric anhydride (disclosed by '893) and maleic anhydride (disclosed by '747) are known in the art as effective agents for carrying out such acylations. Thus, using free-radical maleation to introduce a carboxyl group into the polymer of EP '171 is no more than using an art-recognized means (free-radical maleation) to fulfill an art-recognized need (adding a carboxyl side group to the polymer of EP '171).

The rejection of claims 1, 8, 12, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0952171 (EP '171) in view of US 5149747 ('747) in further view of US 5681846 ('846) in further view of US 5304121 ('121) is maintained for the reasons of record.

Applicant argues that the Examiner has used hindsight reconstruction in combining the four references to make the above rejection.

Applicant's arguments have been fully considered but are not found persuasive.

Reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. In re Gorman, 933 F.2d 982, 18

USPQ2d 1885 (Fed. Cir. 1991)" MPEP § 2145, V. EP '171, '747 and '846 fail to teach a metallic endovascular stent coated with the hydrogel composition. '121 was included in the rejection to show nitinol (metallic) endovascular stents coated with a hydrogel wherein the hydrogel provides controlled release of anti-thrombogenic compounds such as heparin. It would have been obvious to one of ordinary skill in the art to use the polyester hydrogel of EP '171 as the stent coating of the '121 for the reasons given in the previous office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

May 3, 2010